

70585-13

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

P. Leanne Pruett
Agent for Novartis Animal Health US, Inc.
Pyxis Regulatory Consulting
4110 136th St. NW
Gig Harbor, WA 98332

SEP 11 2013

Subject: Novartis Animal Health Child Resistant Packaging and Spot-on Mitigation Amendments
EPA Reg. Nos. 70585-11 (EasySpot), 70585-12 (Parastar), 70585-13 (Parastar Plus)
EPA Decision Nos. 471126, 471379, 473239, and 471113

Dear Ms. Pruett,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the information submitted to support the inclusion of additional retail package sizes and corresponding label changes are accepted. Additionally, per your request of August 27, 2013, the primary brand names of "EasySpot for Cats", "Parastar for Dogs", and "Parastar Plus for Dogs" for EPA Reg. Nos. 70585-11, 70585-12, and 70585-13 respectively, are accepted as the primary brand names, and the previous primary brand names "EasySpot", "Parastar", and "Parastar Plus" are no longer active. Lastly, the label requirements for these products listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. Please submit final printed labels incorporating these changes to the Agency within 30 days of the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action.

EPA also received your February 8, 2013, request to replace the conditional time-limited registrations with unconditional registrations. At this time, EPA does not have enough information to warrant the removal of these conditions of registration. If Novartis Animal Health wishes to remove the time limitations altogether, please submit to the Product Manager an amendment application for each product to change the terms and conditions of the registration. Please include with your submission a written rationale for the removal of the time limitation. As you may remember, the Agency included this time limitation as a condition of registration for your products to allow for the post-market surveillance of these products. Therefore, we recommend that you include in your rationale the following information, along with any additional information or analyses you think would be helpful to the Agency (e.g.; tables, charts, information on stewardship activities, etc...):

- A summary and analysis of the incidents received associated with these products, including information on the following:
 - A comprehensive analysis of incident rates per doses distributed;

- An analysis of historical incident trends since the products' release into the marketplace;
- An analysis of historical incident trends by weight range of animal, breed, weight range of product, etc...
- If these products are also registered in the European Union or Canada, information on incident rates per doses distributed and trends in those countries.

Please also note that requests to remove the expiration date condition are not subject to PRIA fees and do not have to be submitted under PRIA. However, these would also not be considered 90-day, fast-track submission in order to allow the EPA enough time to fully evaluate the information provided. After receiving these submissions, the EPA will consider the incidents received since the initial registration; review the information and rationale provided; and make a decision on the request.

In the interim, the time-limited registrations for these products are extended two years from the date of this letter. If registration extension requests are not received prior to that date, the registration of these products will expire. If a review of the previously submitted enhanced incident data indicates that there is a concern with any of these products, EPA may choose to take further regulatory action at that time.

Per the additional requirements of September 30, 2011 letter, you must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Reevaluation Division, Mail Code 7508P.

The following is a list of information that must be included in the quarterly reports for each incident:

- EPA Registration Number
- Product name (brand name)
- Lot #
- Where purchased: internet, store, veterinarian
- Active Ingredient(s)
- Weight range for product

- Date on which incident occurred. (mm/dd/yyyy)
- State in which the incident occurred. (standard 2 letter abbreviation)
- Registrant case #

- Species: dog, cat, other (specify)
- Breed: (as reported by pet owner)
- Age: months or years
- Sex: M, F, or neutered
- Weight: pounds

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Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.

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- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

Stamped copies of the labels are enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Labels stamped "Accepted"

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[] - Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels

[FRONT CARTON LABEL - MASTER LABEL COPY STARTS]

Parastar Plus™

For Dogs

Apply only to puppies over 12 weeks old and over [4] [23][45][89] lbs.
[[*alternate language*] Apply only to puppies 12 weeks or older and over [4] [23][45][89] lbs.]

[Mosquitoes]

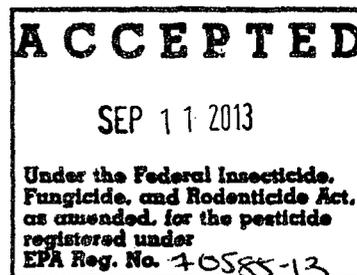
- [Kills mosquitoes] [within 24 hours for up to the first 7 days after application, and within 48 hours for up to 28 days]
- [Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]
- [Kills mosquitoes]

[Chewing Lice]

- Kills chewing lice]
- Rapidly eliminates infestations of chewing lice]

[Fleas]

- [Quickly] [K][k]ills fleas]
- Kills fleas fast]
- Kills adult fleas] [in as little as 1 hour] [!] [for up to three months]
- Kills newly emerged adult fleas (starts killing in as little as 1 hour) before they lay eggs]
- Kills fleas [in as little as 1 hour], which may be a source of flea allergy dermatitis] [or, flea bite anemia]
- Kills fleas [in as little as 1 hour]]
- Kills fleas [in as little as 1 hour] Up to [4 weeks] [1 month] [30 days]!]]
- If dog is at high risk of flea reinfestation, apply once a month]
- Starts [[killing] [to kill]] fleas in [as little as] [just] [5] [15] [minutes] [1 hour] [after application]]



[Multiple Infestations]

- Kills chewing lice and controls mites that may cause sarcoptic mange]
- [Kills chewing lice and] [A][a]ids in control of mites that cause sarcoptic mange]
- Controls mites, a leading cause of sarcoptic mange]
- Starts [[killing] [to kill]] fleas and ticks in [just] [5] [15] [minutes] [1 hour] [after application]]
- [Quickly] [K][k]ills fleas and ticks]
- Flea [&] [and] Tick Control only for Dogs [&] [and] Puppies 12 weeks old and older] [more than 12 weeks of age]

- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)] [and] chewing lice [&] [and] [mosquitoes]
- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [and kills Mosquitoes], [and kills chewing lice]
- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills chewing lice [&] [and] [mosquitoes]
- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [mosquitoes,] and chewing lice]
- Kills [and] Fleas, Ticks, [and kills chewing lice] [and] [mosquitoes]
- Monthly flea, tick, mosquito, and chewing lice application
- Kills Fleas (starts killing in as little as 1 hour), Ticks (starts killing in as little as 1 hour), mosquitoes, and lice]
- [4 Week] [1 month] [30 day] [Flea and Tick Application]
- [Four (4) Week] [1 month] [30 day] [Flea, Tick, Mosquito and Chewing Lice Application]
- Kills Fleas (starts killing in as little as 1 hour) and Ticks (starts killing in as little as 1 hour) for up to [4 weeks] [1 month] [30 days]!
- [Once A Month Flea and Tick Application]
- Use Parastar Plus™ [For Dogs] monthly to control Ticks (starts killing in as little as 1 hour) and chewing lice]
- Monthly flea, tick, mosquito, and chewing lice protection.]
- Flea & Tick Control only for Dogs & Puppies 12 weeks old and older] [more than 12 weeks of age]
- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills chewing lice & mosquitoes]
- Starts [[killing] [to kill]] fleas and ticks in as little as [5][15][minutes] [1 hour] [and continues to kill for a month]]

[Ticks]

- [Quickly] Kills Ticks]
- Starts [[killing] [to kill]] ticks in just [5] [15] [minutes] [1 hour] [after application]]
- Kills Ticks (starts killing in as little as 1 hour) including those that may transmit Lyme disease]
- Kills Ticks (starts killing in as little as 1 hour) for Up to [4 weeks] [1 month] [30 days]!
- Kills] Deer Ticks [that may transmit Lyme Disease,] for up to [4 weeks] [1 month] [30 days]]
- Kills Ticks (starts killing in as little as 1 hour)]
- Kills Deer Ticks for up to [4 weeks] [1 month] [30 days]]
- Kills [Brown Dog Ticks], [American Dog Ticks,] [and Lone Star Ticks] ([starts killing] in as little as 1 hour) [(*Rhipicephalus sanguineus*)] for up to [4 weeks] [1 month] [30 days]]
- Kills [Brown Dog Ticks], [(*Rhipicephalus sanguineus*)] [(starts killing] in as little as [5] [15] [minutes] [1 hour]]) for up to [4 weeks] [1 month] [30 days]]
- Kills American Dog Ticks [and] [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]]

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- [•Prevents and control reinfestation of listed pests] [for] [30 days] [1month]]
- [• Kills ticks that may transmit Lyme disease, Rocky Mountain Spotted fever, ehrlichiosis, babesiosis, bartonellosis, anaplasmosis and hepatolzoonosis]

[All Others]

- [•For use only on Dogs and Puppies [12 weeks of age or older] [more than 12 weeks of age]] and weighing 4 [to] [-] 22 lbs.
- [•For use only on Dogs [4 [to] [-] 22 lbs], [23[-][to]44 lbs], [45[-][to]88 lbs], [89[-][to]132 lbs]
- [•Fast Acting]
- [•Dogs can be bathed 24 hours after application]
- [•Long Lasting]
- [•Remains effective, even after bathing, water immersion, or exposure to sunlight]
- [•Convenient spot application]
- [•Fast Action against chewing lice infestations]
- [•Controls mites that may cause Sarcoptic Mange]
- [• One Application] [• Two Applications] [• Three Applications] [• Four Applications] [• Five Applications] [• Six Applications] [• Twelve Applications] [• Twenty-Four Applications] and/or [1 Month Supply] [2 Month Supply] [3 Month Supply] [4 Month Supply] [5 Month Supply] [6 Month Supply] [12 Month Supply] [24 Month Supply] or [4 Week Supply] [8 Week Supply] [12 Week Supply] [16 Week Supply] [20 Week Supply] [24 Week Supply] [48 Week Supply] [52 Week Supply] [104 Week Supply] or [• [1][2][3] [4] [5] [6] [12] [24] applications]
- [• Best if used year round!]
- [• (ICON Showing 4 Week Protection)]
- [• 4 Week Dose!] [in Child Resistant Packaging]
- [• 1 Month Dose!] [in Child Resistant Packaging]
- [•Fipronil (9.8%) + Cyphenothrin (5.2%)]
- [•A fipronil and cyphenothrin product]
- [•[1] [2] [3] [4] [5] [6] [12] [24] [Easy-to-Use] Applications!] [in Child Resistant Packaging]
- [• Easy to Use [Application]] [in Child Resistant Packaging]
- [• Specially Formulated for use only on Dogs and Puppies 12 weeks of age or older]
- [• [Free] Calendar Stickers Inside!]
- [• [Free] Calendar Stickers Inside]
- [• Apply once every [4 weeks] [month] [30 days]!]
- [• Dogs can be bathed 24 hours after squeeze-on is applied]
- [• Waterproof]
- [•Can be used only on puppies 12 weeks of age and older][more than 12 weeks of age]
- [•Monthly application reminder card inside]

- [For use ONLY on Dogs & Puppies] [12 weeks or older] [and weighing 4 [to][-]22 lbs.]**
- [For use only on Dogs weighing 23[-][to]44 lbs.]**
- [For use only on Dogs weighing 45[-][to]88 lbs.]**
- [For use only on Dogs weighing 89[-][to]132 lbs.]**

ACTIVE INGREDIENTS:

Fipronil.....	9.8%
Cyphenothrin.....	5.2%
OTHER INGREDIENTS:	<u>85.0%</u>
TOTAL:	100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See [Back][or][Side] [Label Panel[s] [or] [insert] for full Directions for Use, First Aid and Precautionary Statements

NET CONTENTS:

- [Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24] [Twenty-Four] [-] 0.023 fl oz (0.67 ml) applicators
- [Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24] [Twenty-Four] [-] 0.045 fl oz (1.34 ml) applicators
- [Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24] [Twenty-Four] [-] 0.091 fl oz (2.68 ml) applicators
- [Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24] [Twenty-Four] [-] 0.136 fl oz (4.02 ml) applicators

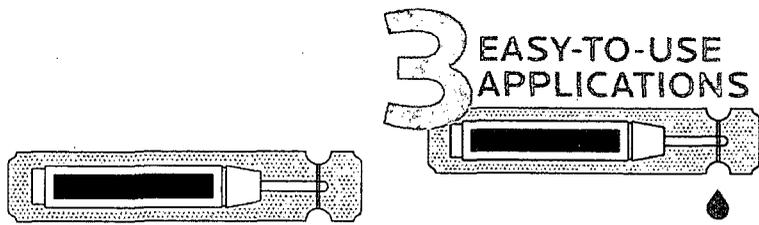


[Front Panel Cat Prohibition Icons – 1.5 x 1.5 cm]

[Optional: Example pictograms that may or may not be found on the printed label]



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[FRONT CARTON LABEL - MASTER LABEL COPY ENDS]

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[BACK CARTON LABEL - MASTER LABEL STARTS]

[For use only on Dogs & Puppies] [12 weeks of age or older] [and] weighing 4 [to] [-] 22 lbs.]

[For use only on Dogs weighing 23[-][to]44 lbs.]

[For use only on Dogs weighing 45[-][to]88 lbs.]

[For use only on Dogs weighing 89[-][to]132 lbs.]

[Parastar Plus™ For Dogs contains Fipronil and Cyphenothrin to effectively kill [in as little as 1 hour] Fleas, Ticks [(including those that may transmit Lyme Disease)], and kills mosquitoes and (chewing) lice.]

[Parastar Plus™ For Dogs contains Fipronil and Cyphenothrin to effectively [start killing [ticks and] [fleas] in [just] [as little as] [5] [15] minutes [and for up to 30 days.] [kill fleas [(starts killing in [5][15] minutes)] [,] [and] ticks [(starts killing in [5][15] minutes)] [(including those that may transmit Lyme disease)], and kills [mosquitoes][and] chewing lice.]]

[The active ingredients in Parastar Plus™ [For Dogs] work by collecting in the hair follicles and skin oils. This product features a sustained-release formula developed for fast acting [and long lasting] control of fleas, ticks, mosquitoes and chewing lice for up to 30 days on dogs.]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.

[Parastar Plus™ [For Dogs] kills fleas [in as little as 1 hour], ticks [in as little as 1 hour], mosquitoes and chewing lice. [Controls mites that may cause sarcoptic mange.] [Aids in control of mites that cause sarcoptic mange.] Kills deer ticks [that may transmit Lyme disease]. Kills brown dog ticks, American dog ticks, and lone star ticks. [Prevents flea reinfestation.]]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Causes moderate eye irritation. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Individual sensitivities, while rare, may occur after using any pesticide product. Certain medications can interact with pesticides. Do not treat your dog with more than one topically applied pesticide at a time. Overdosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, pregnant, nursing, debilitated or aged dogs.

Side Effects

Monitor your dog after application. [Some dogs may experience temporary startle effects when product is applied.] Dogs may experience some temporary irritation at the site of product application, such as redness, scratching, or other signs of discomfort. If signs of a sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other

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side effects occur, consult your veterinarian or call Novartis Animal Health at 1-800-637-0281. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your dog for the next 24 hours.



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE.

Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

FOR EXTERNAL USE ON DOGS ONLY. Do not allow your dog to ingest this product. Do not apply to puppies less than 12 weeks of age. Do not apply to dogs or puppies weighing less than [4][23][45][89] lbs. For use only on dogs [[&] [and] puppies] [weighing 4 [to][-] 22 lbs.]] [weighing 23 [to] [-] 44 lbs.] [weighing 45 [to] [-] 88 lbs.] [weighing 80 [to] [-] 132 lbs.]. Do not split tubes between dogs. [[*alternate language*] Do not use multiple tubes on one dog.] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. [Do not double-dose dogs weighing greater than 132 lbs.]

How to open: Remove product tube[s] [vial[s]] from the package. [Separate one tube from the others.] Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply: While holding the dog with one hand, use the other hand to apply the solution. Invert the [tube] [vial] and use the open end to part the dog's hair. Apply contents of one [tube] [vial] of Parastar Plus™ [For Dogs] [as a spot to the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail]. Hold the dog for a few seconds to give the solution time to be absorbed into the dog's coat. When finished, wrap the [tube] [vial] in paper and put into the trash. Only one applicator per treatment is needed. Repeat application may be made if necessary, but do not apply more often than once every[[4] [four] weeks] [30 days] [month].

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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container.

If empty: Place in the trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Distributed by: [Manufactured for][Available exclusively from]:

Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-13

EPA Est. No. XXXXX-XX-XXX

[BACK/SIDE CARTON LABEL - MASTER LABEL ENDS]

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[OPTIONAL INSERT – START]

[IF INSERT IS NOT PROVIDED, DETAILS WILL BE ON THE CARTON, WITH A FLAP]

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION Causes moderate eye irritation. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Individual sensitivities, while rare, may occur after using any pesticide product. Certain medications can interact with pesticides. Do not treat your dog with more than one spot on topically applied pesticide at a time. Overdosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, pregnant, nursing, debilitated or aged dogs. Call 1-800-637-0281 for 24-hour assistance.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
READ ENTIRE LABEL BEFORE EACH USE.

Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. Do not allow your dog to ingest this product. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately. FOR EXTERNAL USE ON DOGS ONLY. Do not apply to puppies less than 12 weeks of age. Do not apply to dogs weighing less than 4 lbs. For use only on dogs[&] [and] puppies [weighing 4 [to] [-] 22 lbs.] [weighing 23 [to] [-] 44 lbs.] [weighing 45 [to] [-] 88 lbs.] [[&] [and] weighing 80 [to] [-] 132 lbs.][Do not split tubes between dogs.] [Do not use multiple tubes on one dog.] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. [Do not double-dose dogs weighing greater than 132 lbs.] **Best if used year round.** DO NOT USE ON CATS or animals other than dogs. Separate the treated dog from cats for 24 hours after application. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. Cats exhibiting symptoms from ingestion (excessive salivation and foaming at the mouth) should be taken to the veterinarian immediately. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

How to open: Remove product tube[s] [vial] from the package. [Separate one tube from the others.] Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply: Invert the [tube] [vial] and use the open end to part the dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every [[4] [four] weeks] [30 days] [month].

FREQUENCY OF APPLICATION

Use Parastar Plus™ [For Dogs] monthly for complete control of flea, tick [and] chewing lice [and mosquito] [infestations]. [[Studies show that] Parastar Plus™ [For Dogs] kills adult fleas [starts killing in as little as 1 hour)] [[starts killing] [starts to kill] in [5][15] minutes] [for up to three months]. If your dog is at high risk of flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control ticks[, mosquitoes] and chewing lice. Parastar Plus™ [For Dogs] kills mosquitoes within 24 hours for up to the first 7 days after application, then within 48 hours for up to 28 days. Parastar Plus™ [For Dogs] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

For use only on Dogs Weighing [Between 4 [-] [and] 22 lbs.] [4 [to] [-] 22 lbs.]

{For cartons containing .67ml (0.023 fl. oz.) applicator tubes}

Apply one tube (.67ml)(0.023 fl. oz.) [as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

For use only on Dogs Weighing [Between 23 [-] [and] 44 lbs.] [23 [to] [-] 44 lbs.]

{For cartons containing 1.34 ml (0.045 fl. oz.) applicator tube}

[Apply one tube (1.34 ml)(0.045 fl. oz.)] [as a spot on the dog's back between the shoulder blades.] [from the back of the neck to a point midway between the neck and tail].

For use only on Dogs Weighing [Between 45 [-] [and] 88lbs.] [45 [to][-] 88 lbs.]

For cartons containing 2.68 ml (0.091 fl. oz.) applicator tube}

Apply one tube (2.68 ml)(0.091 fl. oz.) [as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

For use only on Dogs Weighing [Between 89 [-] [and] 132 lbs.] [89[to] [-]132 lbs.]

For cartons containing 4.02ml (0.136 fl. oz.) applicator tube}

FIRST AID	
If In Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
If On Skin Or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

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If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-637-0281.</p>	
<p>NOTE TO PHYSICIAN OR VETERINARIAN Treat patient symptomatically</p>	

WARRANTY

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of NOVARTIS ANIMAL HEALTH US, Inc. (NAHUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NAHUS and Seller harmless for any claims relating to such factors.

NAHUS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or NAHUS, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW NAHUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with State law, in no event shall NAHUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NAHUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NAHUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

[If you have questions or comments about this product, please write: Novartis Animal Health US, Inc., (address).]

For Technical Information, call 1-800-637-0281 [For more information] [Hours of service]

17/19

Non-Emergency call (number) [Made in USA]

Distributed by: [Manufactured for][Available exclusively from]:
Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-13
EPA Est. No. XXXXX-XX-XXX

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

How to open

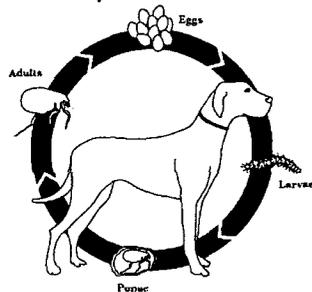
1. Remove product tube[s] [vial] from the package.
2. [Separate one tube from the others.] Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to apply:

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Example Flea life cycle diagram]

Flea Life Cycle



[Look at the Label (Look at the Label icon) 6 Step [Easy] [Parastar Plus™ [For Dogs]] [Spot On] [Squeeze-On] Checklist

- Read the label completely and follow directions

- Weigh your dog
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after application to avoid chance of ingestion
- Do NOT split tubes between dogs [and use the ENTIRE tube contents]

Parastar Plus™ [For Dogs]

[Monthly reminder card] [Fill out this reminder card with your dog's name and the date each treatment should be given to your dog as a reminder to reapply Parastar Plus™ [For Dogs] every 30 days.]

[Apply Parastar Plus™ [For Dogs] monthly for continuous protection against Fleas, Ticks, [and] chewing lice [and mosquitoes].]

[For year round protection apply Parastar Plus™ [For Dogs] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[[First] [1st]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Second] [2nd]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Third] [3rd]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Fourth] [4th]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Fifth] [5th]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Sixth] [6th]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Seventh] [7th]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Eighth] [8th]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Ninth] [9th]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Tenth] [10th]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Eleventh] [11th]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Twelfth] [12th]] [dose] [Application] (Empty blank for owner to fill in date)]

[calendar stickers with brand name] [Place stickers on your calendar as a reminder to reapply [brand name] [in 30 days.]

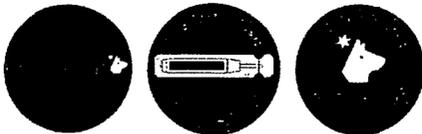
[Visit [web-address] to download a free convenient application for your Smartphone for an electronic calendar reminder]

[calendar stickers with Parastar Plus™ [For Dogs]]

[[1] [2] [3] [4] [5] [6] [12] [24]-month] [application tracker]

[Enclosed for your convenience are [one][1] [two] [2] [three] [3] [four] [4] [five] [5] [six] [6] [seven] [7] [eight] [8] [nine] [9] [ten] [10] [eleven] [11] [twelve] [12] stickers.] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply Parastar Plus™ [For Dogs] every 30 days.]

[Optional Example graphics for calendar stickers, reminder cards, and/or magnets.]



[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30

days the reminder light will blink, reminding you to reapply Parastar Plus™ [For Dogs]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Optional: Example pictograms that may or may not be found on the printed label]



[INSERT – END]

[EPA Approval date]